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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,698	02/08/2002	Dirk Muessig	7163-38	2519

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EXAMINER

LEUBECKER, JOHN P

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 11/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/072,698

Applicant(s)

MUESSIG ET AL.

Examiner

John P. Leubecker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 48-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 48-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 52 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 52 and 55, the term "angioplasty" as describing the balloon is indefinite with respect to its intended meaning since the specification fails to describe an "angioplasty balloon" (it doesn't even use the word angioplasty). This term will be interpreted as "expandable" as per the specification. The term "angioplasty" should be removed from the claim.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 48-50 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Kranz (U.S. Pat. 6,547,757).

Note ring electrodes (72) in Figure 4 and col.6, line 54 to col.7, line 45.

4. Claims 48-57 are rejected under 35 U.S.C. 102(b, a and e) as being anticipated by Amundson et al. (U.S. Pat 6,178,346).

Referring mainly to Figure 13, Amundson et al. disclose the combination of an annular tube of optical fibers (76,79) around two catheters (84) (col.35, lines 38-51), the combination forming a catheter sheath having a distal catheter portion. Optical fibers (76) are coupled to a light source (86), meeting the limitations of the illumination device within the catheter sheath. Optical fibers (79) are coupled with camera (83), meeting the limitations of the image recording unit. Image processing unit (35), CPU (29), video processor (32) and video console (30) (monitor) meets the limitations of the image reproduction unit. It has already been established that the wavelengths used are ones for which blood has a high transparency (note col.28, lines 13-16, for example). Amundson et al. suggest that the catheters can be "any catheter, such as an angioplasty, ablation or pacing catheter" (col.35, lines 50-51). Amundson et al. also describe pacing catheters as having a ring electrode (which are inherently on the outside surface) (col.9, lines 3-21) and angioplasty catheters has having a balloon (col.2, lines 25-27). Thus, Amundson et al. teaches the combination of elements which meet the limitations of claims 48, 51, 52 and 55. As to claims 49, 53 and 56, although not preferred, Amundson et al. contemplates wavelengths around 650 nanometers (col.24, lines 17-25). As to claims 50, 54 and 57, the optical fibers (76) provide an light waveguide serving to pass illumination from the proximal to distal end. The light waveguide, as shown in Figure 13, is integral with the catheter sheath.

Claim Rejections - 35 USC § 103

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5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 48-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lennox (U.S. Pat. 5,575,772) in view of Amundson et al.

Referring mainly to Figure 18, Lennox disclose a catheter sheath (10), a ring electrode (18) integral with an outer surface of the catheter sheath at the distal catheter portion, and a balloon (22) integral with the catheter sheath and at the distal catheter portion. An electrode, by its inherent nature, it capable of both delivering and receiving an electrical signal. For aid in placement of the electrodes and balloon, an ultrasound transducer (150) is inserted into the catheter sheath (col. 4, lines 58-64). Thus, Lennox fails to disclose a infra-red light imaging device (which includes an illumination device, image recording unit and image reproduction unit as claimed). However, Amundson et al., by pointing out the deficiencies of using ultrasound in angiography, angioplasty and catheter ablation for visualization (col.2, line 13 to col.3, line 67) suggests use of infrared light imaging instead (col.6, lines 21-24, col.8, lines 35-67, col. 9, lines 1-37). Note specifically the suggestion that the infrared visualization would make catheter ablation procedures more precise and shorter in duration (col.9, lines 26-35). Thus, this would suggest and properly motivation one of ordinary skill in the art to consider using the principles of infrared light visualization in place of the ultrasound used in the Lennox device to enhance image quality. As pointed out above in the description of Amundson et al. (note rejection under

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35 U.S.C. 102), the limitations of the illumination device, image recording unit and the image reproduction unit would be met. Furthermore, the particular wavelength ranges and the longitudinally extending light waveguide would be met as described above.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Barrington et al. (U.S. Pat. 4,602,645)--note pacing catheter with ring electrodes and balloon (Fig.6).

Salo et al. (U.S. Pat. 4,587,975)--note angioplasty catheter with ring electrodes and balloon (Fig.1).

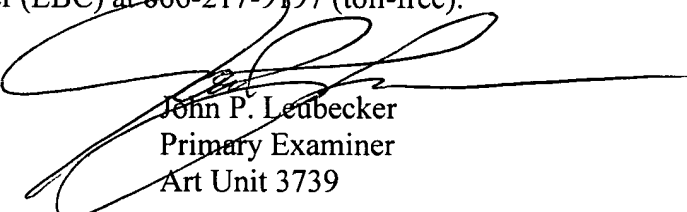
8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (571) 272-4769. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John P. Leubecker
Primary Examiner
Art Unit 3739

jpl